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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/536,592	02/02/2006	Venkata Satya Nirogi Ramakrishna	SUB 0005 US	9209
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IPHORGAN, LTD. 1130 LAKE COOK ROAD SUITE 240 BUFFALO GROVE, IL 60089			EXAMINER YOUNG, SHAWQUITA	
			ART UNIT 1626	PAPER NUMBER
			MAIL DATE 11/14/2008	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/536,592

**Applicant(s)**

RAMAKRISHNA ET AL.

**Examiner**

SHAWQUIA YOUNG

**Art Unit**

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 15 July 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) 5-19 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1 and 2 is/are allowed.
- 6) ☒ Claim(s) 3 and 4 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/CDC)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_
- Paper No(s)/Mail Date \_\_\_\_\_

### **DETAILED ACTION**

Claims 1-19 are currently pending in the instant application. Applicants have added claims 18 and 19 in an amendment filed on July 15, 2008.

#### **I. *Response to Arguments/Remarks***

Applicants' amendment, filed on July 15, 2008, has overcome the rejection of claims 1-4 under 35 USC 112, first paragraph for not being enabled for solvates, polymorphs or metabolites of the instant compounds (in part); the rejection of claim 2 under 35 USC 112, first paragraph for not being enabled for a hydrate of the instant compounds; the rejection of claims 1 and 2 under 35 USC 112, second paragraph as being indefinite; the rejection of claim 2 under 35 USC 112, second paragraph as being indefinite and the rejection of claim 2 for lacking antecedent basis. The above rejections have been withdrawn.

The Examiner has maintained the rejection of claims 3 and 4 under 35 USC 112, first paragraph for not being enabled for polymorphs of the instant compounds (in part) because Applicants have failed to delete the term "polymorphs" in claim 3.

#### **II. *Rejection(s)***

##### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3 and 4 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a compound of formula (I) or stereoisomers, geometric forms, N-oxide or pharmaceutically acceptable salts does not reasonably provide enablement for polymorphs of a compound of formula (I). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

As stated in the MPEP 2164.01 (a), "There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue."

In In re Wands, 8 USPQ2d 1400 (1988), factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described. They are:

1. the nature of the invention,
2. the state of the prior art,
3. the predictability or lack thereof in the art,
4. the amount of direction or guidance present,
5. the presence or absence of working examples,
6. the breadth of the claims,
7. the quantity of experimentation needed, and
8. the level of the skill in the art.

In the instant case

***The nature of the invention***

The nature of the invention is a pharmaceutical composition comprising a compound of formula (I), its stereoisomers, its geometric forms, its N-oxides, its polymorphs or its pharmaceutically acceptable salts.

***The state of the prior art***

It is the state of the prior art that the term "polymorphism" is defined as the existence of different solid forms (modifications) of a compound which have the same chemical composition but different structures and thus different physical and sometimes also chemical properties (Concise Encyclopedia Chemistry 1993). It is the state of the prior art that under any given pressure and temperature, other than the conversion points, only one modification is stable, the one with the lowest vapor pressure. Often the conversion rate in the solid phases is so slow that even modifications which are unstable under the conditions can be kept for a long time in their metastable state. This conversion rate can depend on the rate of temperature change or pressure change (Concise Encyclopedia Chemistry 1993). As defined, the instant claims read on any polymorph of the claimed compound which is broader than the enabling disclosure. There is no support or guidance to show that one can even make a polymorph of the instant compounds and would therefore require undue experimentation.

***The amount of direction or guidance present and the presence or absence of working examples***

There is little direction or guidance present in the specification or working examples present in the specification are that defines or relates to what polymorphs are being included in the elected invention.

***The breadth of the claims***

The breadth of the claims is a compound of formula (I), its stereoisomers, its geometric forms, its N-oxide, its polymorphs or its pharmaceutically acceptable salts.

***The quantity of experimentation needed and the level of the skill in the art***

While the level of the skill in the pharmaceutical art is high, the quantity of experimentation needed is undue experimentation. One of skill in the art would need to prepare compounds with both similar and different structural radicals without any direction as to what structural radical is needed.

The level of skill in the art is high without showing or guidance as to how to make polymorphs of a compound of formula (I) it would require undue experimentation to figure out the starting materials, solvents, temperatures and reaction times that would provide polymorphs of the above compounds.

To overcome this objection, Applicant should submit an amendment deleting the terms "polymorphs".

**III. Conclusion**

**THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shawquia Young whose telephone number is 571-272-9043. The examiner can normally be reached on 7:00 AM-3:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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/Shawquia Young/

Examiner, Art Unit 1626

/Kamal A Saeed/

Primary Examiner, Art Unit 1626